

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
FLW-LHG
MDL No. 2738**

THIS DOCUMENT RELATES TO ALL CASES

**THE PLAINTIFFS' STEERING COMMITTEE'S REPLY BRIEF TO
DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON
CONSUMER INC.'S MEMORANDUM OF LAW IN OPPOSITION TO
PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS OF
ROBERT KURMAN, M.D.**

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I. INTRODUCTION

The Plaintiffs’ Steering Committee (“PSC”) submits this reply brief in further support of its motion¹ to exclude the causation opinions of Dr. Robert Kurman. This reply brief addresses issues raised in *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Memorandum of Law in Opposition to Plaintiffs’ Motion to Exclude the Opinions of Robert Kurman, M.D.* (ECF No. 9872) (“Defs. Opp”).²

Dr. Kurman’s general causation and biological plausibility opinions lack the necessary foundational support and methodology to satisfy *Daubert* standards. His opinions amount to nothing more than unsubstantiated *ipse dixit*.³ J&J’s attempts to prop up Dr. Kurman’s opinions actually reveal more deficiencies.

First, Dr. Kurman failed to undertake a thorough and adequate review of the relevant scientific literature and information in forming his opinions. Instead, for

¹ *Plaintiffs’ Steering Committee’s Memorandum of Law in Support of its Motion to Exclude the Opinions of Robert Kurman, M.D.* (“PSC Brief”) (ECF No. 9734-1).

² Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc. are referred to collectively herein as “J&J.”

³ The term *ipse dixit* translates as “he himself said it” and refers to “dogmatic and unproven statement[s].” *Schulenberg v. BNSF Railway Co.*, 911 F.3d 1276, 1283 at n.3 (10th Cir. 2018) (citing *Ipse Dixit*, BLACK’S LAW DICTIONARY, 10th ed. 2014). “Unfounded extrapolations not supported by, or sufficiently related to, scientific data or expertise should be rejected. . . opinion that is connected to existing data only by the *ipse dixit* of the expert need not be admitted.” *In re Zyprexa Prod. Liab. Litig.*, 489 F. Supp. 2d 230, 284 (E.D.N.Y. 2007) (citations and quotations omitted).

the most part, Dr. Kurman opted to rely upon his “experience” as the basis for his opinions. Although J&J points to Dr. Kurman’s citation to some medical literature in defense of the PSC’s claim that he failed to apply an appropriate methodology in support of his opinions, close examination shows that to the extent Dr. Kurman actually reviewed the referenced literature, his citations fail to support the opinions that the PSC challenges or Dr. Kurman’s criticisms of Dr. Kane, each of which remain unsupported. In addition, and in contrast to Dr. Kane (who explained and supported all of her principal opinions), Dr. Kurman cannot rely only on his alleged experience to meet the *Daubert* standard. *Daubert* case law is clear that not only must an expert be qualified in order to offer an admissible expert opinion, but the expert must also demonstrate a proper methodology that produces a reliable expert opinion. “Experience” alone is not sufficient to meet the *Daubert* standard. Even if it were, Dr. Kurman does not have the appropriate experience regarding talcum powder, asbestos and related diseases to support his challenged opinions.

Second, Dr. Kurman’s consideration of the evidence was substantially and *materially* incomplete. An expert offering causal opinions must consider all relevant evidence, and a “causal conclusion requires examination” of scientific studies and literature “as a whole.”⁴ His opinions are based on classic “cherry-picking,” *i.e.*,

⁴ *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002) (“...all of the relevant evidence must be gathered, and the assessment or weighing of that evidence

he did not acknowledge, consider, explain, or reconcile multiple relevant published studies (*both* epidemiological *and* biological studies) that are inconsistent with his general causation and biological plausibility opinions. Ironically, J&J's only response to this assertion is to call the omitted studies "irrelevant."⁵ But the studies are not only relevant, they are some of the seminal studies and peer-reviewed publications on the topic of talcum powder and ovarian cancer. By cherry-picking the science and ignoring important studies that are contrary to his opinions, Dr. Kurman failed to "adequately account for contrary evidence" and, thus, his "methodology is not reliable or scientifically sound,"⁶ and his resulting opinions are simply "based on subjective belief."⁷

Third, throughout his deposition, Dr. Kurman made clear that he employed a "convincing" standard for assessing causation. This heightened standard of certainty, which infects all his opinions, will not be helpful and will certainly confuse a jury who must decide the issues based on a preponderance of evidence standard. J&J does not challenge that it is unacceptable for their expert to use a standard

must not be arbitrary, but must itself be based on methods of science."); *In re Zolof Prod. Liab. Litig.*, 26 F. Supp. 3d 449, 460-61 (E.D. Pa. 2014).

⁵ Defs. Opp. at 2, 12, 16, 23, 32.

⁶ *In re Zolof*, 26 F. Supp. 3d at 460-61 (excluding expert's opinion where expert report "selectively discuss[es] studies" in favor of his or her opinion while failing to consider conflicting studies; the court referred to this as "cherry-picking").

⁷ *Id.* at 461-2.

beyond a preponderance but, instead, argues that Dr. Kurman did not actually use a heightened standard. Unfortunately, J&J's argument is based on their own cherry-picked and strained interpretation of Dr. Kurman's testimony. The plain meaning of Dr. Kurman's testimony, detailed in the PSC's prior briefing,⁸ is that his causation opinions were based on his use of a more exacting standard of certainty, making his expert opinions impossible for a jury to process using the proper evidentiary standards

Fourth, Dr. Kurman's critiques of Dr. Kane's opinions fail to meet the *Daubert* reliability standards. Those opinions cover four subjects: (1) similarities between asbestos/mesothelioma and talcum powder/serous invasive ovarian cancer; (2) migration of talcum powder to the ovaries; (3) inflammation and ovarian cancer; and (4) detection of talcum powder in the ovaries. J&J is unable to identify any semblance of a reliable methodology in Dr. Kurman's critique of Dr. Kane.

⁸ See PSC Brief at 17-21.

II. ARGUMENT

A. DR. KURMAN SHOULD BE PRECLUDED FROM OFFERING OPINIONS BECAUSE HE FAILED TO IMPLEMENT ANY APPROPRIATE METHODOLOGY TO FORM HIS OPINIONS

1. Dr. Kurman's General Causation Opinions Are Not Grounded In Sound Methodology

Dr. Kurman's general causation opinions, some of which were not disclosed in his initial Rule 26 report, do not come close to meeting the *Daubert* reliability standards because he failed to apply an appropriate methodology to inform those opinions. None of the cases cited by Defendants provide support to overcome this deficiency.⁹

The Third Circuit deems expert opinions unreliable where the expert ignores material evidence when formulating his or her opinions, and that is what happened here, in spades. This is particularly true with respect to epidemiological studies. “When one is interested in human causation, the most relevant evidence will come

⁹ J&J asserts that experts may offer opinions at trial that are not contained in their expert report (Defs. Opp. at 8). However, none of the cited cases provide a “get out of jail free” card that would allow an expert to offer opinions that do not meet *Daubert* reliability standards. Further, and because “[i]t is axiomatic that an expert may not present *new* opinions on topics not timely... disclosed in the expert's report,” but this is exactly what Dr. Kurman attempted to do *Krys v. Aaron*, 112 F. Supp. 3d. 181, 207 (D.N.J. 2015) (emphasis added) (precluding expert's testimony when such testimony “exceed[ed]” what was included in his expert report; the court stated pursuant to Rule 26(a)(2)(B) an expert report *must* contain “a complete statement of all opinions to be expressed and the basis and the reasons therefore.”).

from human epidemiological studies,” and “experts asserting causation opinions must thoroughly analyze the... epidemiological research and explain why that body of research does not contradict or undermine their opinion.”¹⁰ Also, as originally argued by the PSC,¹¹ Dr. Kurman failed to consider vital cell biology studies *and* epidemiological studies. J&J does not challenge the PSC’s claim that Dr. Kurman failed to meet this standard. To the contrary, J&J concedes that Dr. Kurman did not read relevant epidemiological studies, but argues that it was not necessary because the “studies would not provide any assistance to a pathologist approaching biologic plausibility.”¹²

Compounding his failure to review relevant scientific literature, Dr. Kurman testified that in order to reach reliable conclusions about general causation, an expert

¹⁰ *In re Zolofit*, 26 F.Supp. 3d at 466, 475. Also, as noted in the *Reference Manual*, when assessing causation, “careful assessment of the methodological validity and power of the epidemiologic evidence *must be* undertaken, ...” along with consideration of other lines of evidence. *Ref. Man.* at 564-65 (emphasis added). *Accord, In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 132 (D. Mass. 2009) (describing epidemiological studies as “powerful evidence of causation.”).

¹¹ See PSC Brief at 6.

¹² Defs. Opp. at 17-18. The PSC also argued that Dr. Kurman’s opinion about there being “no evidence” supporting general causation does not meet *Daubert* standards because such an opinion, by definition, requires that the expert actually consider all of the evidence, and Dr. Kurman failed to do so. J&J offers no response and apparently concedes this point.

would have to apply the Bradford Hill causation guidelines.¹³ However, Dr. Kurman failed to meet his own standard: he did not conduct a Bradford Hill causation analysis in his report, ignoring his own required methodology and failing to adhere to the requirements under *Daubert*. Where an expert does not follow his own methodology, the testimony should be excluded.¹⁴

To make up for Dr. Kurman's lack of an articulable methodology, J&J argues that Dr. Kurman's opinions are reliable because of his pathology experience.¹⁵ But without support from the science, the claim of experience requires closer scrutiny. By his own admission, Dr. Kurman is unqualified to offer expert opinions in cancer or cell biology as it relates to talcum powder exposure. Dr. Kurman testified he is

¹³ Dr. Kurman testified "...this litigation is about... does talc cause ovarian cancer. And... everyone agrees... in order to come to a conclusion..., is to apply the Bradford Hill criteria." Kurman Dep. at 47:9-17 (Exhibit B to PSC Brief); see *In re Zolof Prod. Liab. Litig.*, 858 F.3d 787, 796 (3d Cir. 2017) (internal quotations omitted) ("[t]o ensure that the Bradford Hill/weight of the evidence criteria is truly a methodology, rather than a mere conclusion-oriented selection process ... there must be a scientific method of weighting that is used and explained.").

¹⁴ *In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir. 1999). Accord, *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 560 (W.D. Pa. 2003); see also *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, No. CIV.A. 10-143, 2013 WL 3487560, at *22 (W.D. Pa. July 12, 2013) ((expert's failure to apply the Bradford Hill criteria, which he has called the "gold standard" in this field, when he ordinarily does so is significant) citing *Rimbert v. Eli Lilly & Co.*, No. CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 (D.N.M. July 21, 2009) ("That Dr. Jackson chose not to apply the methodology that she personally considers to be the standard in her field to assess causation [Bradford Hill criteria] undermines the reliability of her testimony.")).

¹⁵ Defs. Opp. at 2, 3, 11-17, 23-25, 30, 33-34, 36, 40.

not an expert in cancer biology,¹⁶ he has never studied the effects of talcum powder and/or asbestos on gynecologic tissue (or any tissue for that matter),¹⁷ has never looked at talcum powder in tissue under a microscope,¹⁸ has never published or even lectured on any topic related to talcum powder¹⁹ and, most importantly, he failed to consider or even read many of the seminal talcum powder cell studies and epidemiology studies in the scientific literature (including many referred to on his supplemental reference list). Dr. Kurman has unquestioned pathology experience, but no experience with talcum powder (and its constituents of asbestos, fibrous talc, and heavy metals) and their association with ovarian cancer.²⁰ In short, Dr. Kurman cannot offer legitimate, reliable opinions on general causation of talcum powder, asbestos and ovarian cancer when he acknowledges he is not an expert in cancer biology, and he did not even review the cellular biology data or employ a reliable methodology in reaching his general causation opinions.

¹⁶ Kurman Dep. at 35:12-17.

¹⁷ *Id.* at 23:10-16 and 26:10-16.

¹⁸ *Id.* at 23:10-16 and 25:14-18

¹⁹ *Id.* at 23:5-9.

²⁰ *See generally Rose v. Truck Centers, Inc.*, 388 Fed. Appx. 528, 533 (6th Cir. 2010) (“[t]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question”) (internal quotes omitted)).

2. Dr. Kurman's Biological Plausibility Opinions Regarding Talc And Ovarian Cancer Are Unreliable Because Dr. Kurman Failed to Use An Acceptable Methodology

A biological plausibility opinion is admissible only if it is “derived from *and* supported by reliable scientific knowledge and reasoning.”²¹ To be admissible, Dr. Kurman’s opinions must have been formed based on “ample scientific support” employed in each step of his methodology, and he must have explained each step with sufficient “sound scientific reasoning.”²²

Defendants also challenge Plaintiffs’ assertion that Dr. Kurman’s report did not disclose biological plausibility opinions, quoting nine statements from Dr. Kurman’s report to support their argument.²³ However, the quoted statements lack scientific support, none mention the words “biological plausibility,” and none disclose Dr. Kurman’s opinion that it is not biologically plausible for talcum powder to cause ovarian cancer.²⁴

²¹ *In re Abilify Prod. Liab. Litig.*, 299 F. Supp. 3d 1291, 1308 (N.D. Fla. 2018).

²² *In re Zolofit*, 858 F.3d at 800 (“[T]he fact that [an expert] unreliably applied the techniques underlying the weight of the evidence analysis and the factors of the Bradford Hill analysis satisfies the standard for inadmissibility”).

²³ Defs. Opp. at 6-7.

²⁴ A review of each of the nine statements reveals that none constituted biological plausibility opinions. For example, the first statement was that it is unlikely that talc causes all of the diverse group of “neoplasms” grouped together as ovarian cancer. That is not the same as saying that it is not biologically plausible for talc to cause ovarian cancer. The second statement pertained to differences between talc and asbestos; it was not a biological plausibility opinion. The third is an opinion that talc-induced inflammation is different from the type of inflammation that the studies have

J&J argues that Dr. Kurman's opinions are not based only on *ipse dixit*, pointing out that his report has "more than 100 references and contains more than 150 footnotes substantiating his opinions."²⁵ However, as noted in the PSC Brief at 9, Dr. Kurman admitted that he did not even read many of the materials on his reference lists.²⁶ Nor do the citations in footnotes in his report provide an escape for Dr. Kurman. J&J attempts to show that Dr. Kurman's opinions are "well supported by the relevant scientific literature," but provide just two examples.²⁷ Even if an expert's opinions are supported by relevant scientific literature, *Daubert* demands that the expert have reviewed the literature in forming his or her opinions. How else could they be the expert's opinions? Admittedly, Dr. Kurman did not do so. This failure, alone, warrants the exclusion of Dr. Kurman's opinions on biologic plausibility.

J&J's arguments in support of Dr. Kurman further exemplify Dr. Kurman's ignorance related to the relevant literature. For example, J&J argues that "in

linked to ovarian cancer. The fourth is a statement that he would expect to see evidence of inflammation in the precursor lesions to ovarian cancer, and he has not seen that. Again, this is not the same as saying that it is not biologically plausible for talc induced inflammation to cause ovarian cancer.

²⁵ Defs. Opp. at 2.

²⁶ See Kurman Dep. at 12:11-14:7 (testifying that he did not prepare his supplemental reference list, had not seen it prior to his deposition, and had not read most of the studies and reports identified on the list).

²⁷ Defs. Opp. at 16-17.

discussing the plausibility of talc-induced inflammation as a cause of ovarian cancer, Dr. Kurman cited a study by Heller that found no evidence of response to talc particles (including no foreign body giant cell granulomas) in human ovarian tissue containing talc particles.”²⁸ But J&J (and Dr. Kurman) fail to recognize or note that the Heller study investigators interpreted their results as *providing support* for talc migration to the ovaries.²⁹ The conclusion of the Heller paper was that “[t]he detection of talc in all ovaries demonstrates that it can reach the upper genital tract.”³⁰

By further example, in criticizing Dr. Kane, Dr. Kurman cited a study demonstrating a lower risk of ovarian cancer in women who had tubal ligation

²⁸ Defs. Opp. at 17.

²⁹ Dr. Kurman cited the study to provide support for his opinion that (a) “the studies that Dr. Kane cites as finding talc in ovarian tissue do not support her contention that talc migrated there from the vulva through the reproductive tract,” and (b) “talc found in ovarian tissue could be explained by contamination by other sources.” Kurman Report at 22 (Exhibit A to PSC Brief.).

³⁰ Heller et al., The relationship between perineal cosmetic talc usage and ovarian talc particle burden, *Am. J. Obstet. Gynecol.* 174: 1507-1510 (1996) at 1507 (Exhibit 47 of *The Plaintiffs’ Steering Committee’s Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Motion to Exclude Opinions Related to Biological Plausibility* (ECF No. 9890) (“PSC Biologic Plausibility Opp.”). Notably, Dr. Kurman fails to cite another study published the same year by the same investigators, which demonstrated that “asbestos can reach the ovary” and “asbestos appears to be present in ovarian tissue more frequently and in higher amounts in women with a documentable exposure history [to asbestos]. Heller, *et al.*, Asbestos Exposure and Ovarian Fiber Burden, *Amer J. Indus. Med.* 29:435-439 (1996) (Exhibit 37 to PSC Biologic Plausibility Opp.).

(which would block talc migration to the ovaries). The study (Tiourin 2015) addressed the effect of tubal ligation on epithelial tissue in the fallopian tube, but does not support Dr. Kurman's stated reason for citing it. The authors concluded that the reason that "tubal ligation protects against epithelial ovarian cancers" is a "potential 2-pronged mechanism" including that "it interrupts the conduit and halts ...migration" to the ovary,"³¹ which is the precise opinion of Dr. Kane that Dr. Kurman was trying to discredit. Tellingly, Dr. Kurman published this same observation in the most recent edition of his textbook.³²

Dr. Kurman's testimony and the arguments offered by J&J in opposition to the PSC Brief demonstrate that Dr. Kurman's review of relevant medical literature was not sufficient enough to support his opinions on biologic plausibility.³³ While J&J may be familiar enough with the relevant literature to prepare appropriate reference lists, Dr. Kurman must also familiarize himself with the literature in order

³¹ Tiourin, et al., Tubal Ligation Induces Quiescence in the Epithelia of the Fallopian Tube Fimbria, *Reproductive Sciences*, 22(10):1262-1271 (2015) at 9 of 13 and fn. 23, attached hereto as **Exhibit A**.

³² See Kurman Dep. at 159:22-160:14 (textbook discusses inflammation leading to ovarian cancer "by the introduction of foreign material through the vagina and uterine cavity.")

³³ See *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315-16 (9th Cir. 1995)("[S]omething doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive..."); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 158 (3d Cir. 2000).

to properly opine. His opinions are pure conjecture and unreliable based on his “underlying reasoning and methodology,” or lack thereof.³⁴ It is simply not sufficient to have a “knowledgeable expert” in some particular area of science and “leap to conclusions a party would like the jury to be exposed to.”³⁵ Dr. Kurman’s offering of opinions without a thorough review of the literature attempts to do just that and should not be permitted.

Dr. Kurman’s failure to consider relevant peer reviewed and published papers also warrants exclusion of his opinions because he fails to reconcile the differences between his opinions and those contained in the literature. This failure is fatal to the admissibility of any alleged biologic plausibility opinions. Indeed, “claiming a consistent result without meaningfully addressing [] alternate explanations, . . . undermines reliability” under *Daubert*.³⁶ Dr. Kurman simply ignores “multiple lines of evidence” that point to chronic inflammation as playing an important role in

³⁴ *In re Abilify*, 299 F. Supp. 3d at 1308 (a biological plausibility opinion must be reliable in order to be admissible; each step must have “ample scientific support” and “sound scientific reasoning,” explaining each step to meet the reliability requirement).

³⁵ *Schulenberg*, 911 F.3d at 1283 (affirming the district court’s exclusion of expert testimony where the opinions relied heavily on the expert’s experience in a particular area and the expert’s “report made little or no effort to relate the various standards to [his] conclusions,” and failed to provide sufficient detail to support his opinions).

³⁶ *In re Zolof*, 858 F. 3d at 800 (recognizing the importance of explaining why conclusions are reliable in light of opposing explanations).

causing ovarian cancer, and which are at odds with his opinion.³⁷ The connection between inflammation and cancer, including ovarian cancer, is generally accepted and well-described in the peer-reviewed scientific literature, and Dr. Kurman ignores and fails to reconcile this substantial evidence.³⁸ Indeed, citations to numerous relevant studies were provided to Dr. Kurman as part of the PSC's experts' reports, but he chose not to read them. Dr. Kurman's failure to "adequately account for contrary evidence" means that his "methodology is not reliable or scientifically sound."³⁹

³⁷ *Schulenberg*, 911 F.3d at 1283 (precluding expert's opinions where expert "ignored convenient facts, [which] were based on evidence so removed" from the facts in the case as to be "essentially meaningless," and "lacked the detail necessary to support [the expert's] conclusions.")

³⁸ *See Plaintiffs' Steering Committee's Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson's and Johnson & Johnson Consumer, Inc.'s Motion to Exclude Plaintiffs' Experts' Opinions Related to Biological Plausibility*, Section III (B) (ECF No. 9890); *see also Plaintiffs' Steering Committee's Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson's and Johnson & Johnson Consumer, Inc.'s Motion to Exclude Plaintiffs' General Causation Opinions*, Sections III (A) (2)(b) and (c). (ECF No.9888).

³⁹ *In re Zolof*, 26 F. Supp. 3d at 460-62 (excluding expert's opinion where expert report "selectively discuss[es] studies" in favor of his or her opinion while failing to consider conflicting studies; the court referred to this as "cherry-picking" and resulting opinions are deemed to be "based on subjective belief" and therefore inadmissible.)

Dr. Kurman admitted that he read only one of the many PSC's expert's reports—that of Dr. Sarah Kane.⁴⁰ He did not consider the opinions or, more importantly, the numerous citations to scientific evidence in the reports of the other PSC experts. For example, PSC expert Dr. Clarke-Pearson opined that “[t]here is a clear link between inflammation (resulting in oxidative stress) and cancer risk. This is true for many types of cancer including ovarian cancer.” Dr. Clarke-Pearson cited six peer-reviewed studies in support of his opinion.⁴¹ Dr. Kurman's footnotes and reference list do not include *any* of these sources. Other PSC experts reached the same conclusion based on their review and citation to numerous published studies and peer-reviewed scientific articles, very few of which were considered by Dr. Kurman.⁴²

⁴⁰ Kurman Dep. 13:16-18 (“Q Did you read any other report of plaintiff experts? A No, I did not.”)

⁴¹ Clarke-Pearson Report at 4, Exhibit 5 to PSC Biologic Plausibility Opp.

⁴² Kane Report at 5, Exhibit 48 to PSC Biologic Plausibility Opp. (“Once reaching the ovaries, talcum powder products can cause chronic inflammation, can increase oxidative stress, and can reduce immune response. These are biologically plausible and likely mechanisms for ovarian cancer development and progression.”); Saed Report at 19-20, Exhibit 105 to PSC Biologic Plausibility Opp. (“Johnson's Baby Powder elicits an inflammatory response in normal ovarian and tubal cells and in ovarian cancer cells that can result in the development and the progression of ovarian cancer.”); Wolf Report at 12, Exhibit 3 to PSC Biologic Plausibility Opp. (“The link between inflammation and cancer has been recognized since the 1800s. Inflammation and oxidative stress increase the risk of cancer, including ovarian cancer.” (*citing* two studies)); Carson Report at 10, Exhibit 6 to PSC Biologic Plausibility Opp. (“Once reaching the target tissues, talcum powder and its constituents initiate carcinogenesis via multiple means, including, inflammation

Dr. Kurman also fails to address, explain, or reconcile other scientific evidence that provides “biological explanations” regarding the role of inflammation in causing ovarian cancer that are contrary to his opinions. For example:

- **National Cancer Institute.**⁴³ The published position of the National Cancer Institute (NCI) concerning chronic inflammation and cancer risk, stating: “Over time, chronic inflammation can cause DNA damage and lead to cancer.”
- **Trabert (2014).**⁴⁴ Experts from the Division of Cancer Epidemiology, the Frederick National Laboratory for Cancer Research, and the Division of Cancer Prevention, (each part of NCI) published a peer-reviewed paper reporting study results correlating inflammation markers with the risk of ovarian cancer. The investigators stated in the very first sentence: “Epidemiologic evidence implicates chronic inflammation as a central mechanism in the pathogenesis of ovarian cancer, the most lethal gynecologic cancer among women in the United States.”
- **Shan (2009).**⁴⁵ Citing over 40 references to the published scientific literature, another published paper stated: “Increasing evidence suggests that inflammation contributes significantly to the etiology of EOC [epithelial ovarian cancer].”

with chemotaxis of inflammatory cells, liberation of cytokines, and reactive oxygen species, inactivation of TP53 genetic modulator, inhibition of DNA repair, and long-term promotion.”)

⁴³ National Cancer Institute, Statement on Chronic Inflammation (April 29, 2015), attached hereto as **Exhibit B**.

⁴⁴ Trabert, *et al.* Pre-diagnostic serum levels of inflammation markers and risk of ovarian cancer in the prostate, lung, colorectal and ovarian cancer (PLCO) screening trial. *Gynecol Oncol.* 2014 Nov;135(2):297-304 (referencing the Centers for Disease Control and Prevention, Ovarian Cancer Statistics), Exhibit 69 to PSC Biologic Plausibility Opp.

⁴⁵ Shan, et al, Inflammation: A hidden path to breaking the spell of ovarian cancer. *Cell Cycle* 8:19, 3107-3111; 2009, Exhibit 80 to PSC Biologic Plausibility Opp.

- **Savant (2018)**⁴⁶ This peer-reviewed medical review article, *citing over 200 references* to peer reviewed studies and publications, was published in the medical journal *Cancers*. The co-authors (experts in cell and molecular biology and cancer research) discussed the role of chronic inflammation in causing epithelial ovarian cancer and high-grade serous carcinoma of the ovary—the specific type of ovarian cancer at issue in this litigation. These authors state that inflammation is implicated in all stages of carcinogenesis, from initiation through promotion and progression, stating that “[i]nflammation plays a role in the initiation and development of many types of cancers, including epithelial ovarian cancer (EOC) and high grade serous ovarian cancer (HGSC), a type of EOC. ... These exposure-induced changes promote excessive cell proliferation, ...malignant transformation, and cancer development.”
- **Hallmarks of Cancer.**⁴⁷ Co-authored by noted cancer experts Hanahan and Weinberg, this paper identifies inflammation as one of the “hallmarks” of cancer. “The hallmarks of cancer comprise six biological capabilities acquired during the multistep development of human tumors.” The authors include inflammation as one of the important factors “[u]nderlying these hallmarks” because it “fosters multiple hallmark functions.”

⁴⁶ Savant, *et al*, The Role of Inflammation and Inflammatory Mediators in the Development, Progression, Metastasis, and Chemoresistance of Epithelial Ovarian Cancer, *Cancers* 2018, Exhibit 76 to PSC Biologic Plausibility Opp.

⁴⁷ Hanahan and Weinreb, Hallmarks of Cancer, the Next Generation. *Cell*, 2011, vol 144, issue 5, 646-75, Exhibit 75 to PSC Biologic Plausibility Opp. The authors also stated: “research on the intersections between inflammation and cancer pathogenesis has blossomed, producing abundant and compelling demonstrations of the functionally important tumor-promoting effects... (citing four references which are not addressed or reconciled by Dr. Kurman.)” *Id.*

- **Wu (2009)**⁴⁸ A 2009 human population-based case-control study of ovarian cancer to investigate the role of inflammation in the risk of ovarian cancer. Based on their study and their review of other published studies, the authors wrote: “We conclude that risk of ovarian cancer is significantly associated with talc use,” and “factors associated with inflammation are associated with ovarian cancer risk.”

J&J points to Dr. Kurman’s opinion that the site of origin for ovarian cancer is the fallopian tube, and he has not seen inflammation in the pre-cancerous (“STIC”) lesions there.⁴⁹ But not seeing inflammation in the pre-cancerous STIC lesions is not evidence that inflammation did not occur at an earlier stage, and Dr. Kurman offers no biological explanation for why inflammation would lead to cancer generally, but not lead to cancer in STIC lesions in the fallopian tube. More importantly, even if Dr. Kurman’s observations related to STIC lesions were relevant, he does nothing to reconcile those findings with the myriad peer-reviewed scientific literature that does establish a link between inflammation and cancer, including ovarian cancer.

Notably, Dr. Kurman fails to cite, reference, discuss, or reconcile a peer-reviewed paper published in 2018, where four cancer researcher/co-authors agreed with Dr. Kurman regarding the fallopian tube as the site of origin of most ovarian

⁴⁸ Wu, et al, Markers of inflammation and risk of ovarian cancer in Los Angeles County, *Int J Cancer*, 2009, Exhibit 58 to PSC Biologic Plausibility Opp.

⁴⁹ Defs. Opp. at 22, 30, 41.

cancers (“Most ovarian cancers originate in the fallopian tube with subsequent implantation of malignant cells into the ovary....”),⁵⁰ but disagreed with Dr. Kurman about inflammation as a substantial contributing cause. They concluded based on their study and their review of prior published studies and the published scientific literature, that inflammation played an important role in ovarian cancer development: “[w]e conclude that inflammation is the most likely mechanism” to explain why certain inflammatory processes “contribute to the increased risk of ovarian cancer,”⁵¹ and ovarian cancer risk “can be reduced by suppressing inflammation.”⁵² They stated “most of the factors ...implicated in ovarian cancer ...converge on inflammation as a common denominator.”⁵³

Notably, before being retained as a defense expert in this litigation, Dr. Kurman authored a paper published in *American Journal of Surgical Pathology*, wherein he and his co-authors “postulated” that ovarian cancers are “derived from

⁵⁰ Jia, et al, Inflammation is a key contributor to ovarian cancer cell seeding, *Scientific Reports* (2018) 8:12394, attached hereto as **Exhibit C**.

⁵¹ *Id.*

⁵² *Id.* at 6.

⁵³ *Id.* The researchers cited their study findings that “conditions in the ovary associated with inflammation...contributed to increased seeding of ...cancer cells to the ...tissues surrounding the ovary...” *Id.* They added, “[o]ne successful path to ovarian cancer prevention has been controlling ...inflammation,” and they cited “[e]pidemiologic data that ...anti-inflammatory drugs ... can be beneficial in the prevention of multiple cancers, including ovarian (citing studies).” *Id.*

PTH” (papillary tubal hyperplasia), which Dr. Kurman considers a precursor to ovarian cancer.⁵⁴ Dr. Kurman wrote that PTH “appears to be induced by chronic inflammation,”⁵⁵ and “[i]t is well known” that “[c]hronic inflammation induces proliferation of tubal epithelium that can progress to PTH in some women.”⁵⁶ Dr. Kurman cites to this paper in his report but does not reconcile it with his changed opinion about inflammation.⁵⁷

A cornerstone of sound scientific methodology demands that an expert make an “effort to account” for alternative and contrary explanations “for the effect whose cause is at issue.”⁵⁸ Dr. Kurman should not be permitted to testify about a topic that he has little knowledge of or has failed to research, especially where he has failed to

⁵⁴ See Kurman Report at 3 and 4, n. 20.

⁵⁵ Kurman, et al, Papillary Tubal Hyperplasia. The Putative Precursor of Ovarian Atypical Proliferative (Borderline) Serous Tumors, Noninvasive Implants and Endosalpingiosis, *Am J Surg Pathol*. 2011 Nov; 35(11): 1605–1614, attached hereto as **Exhibit D**.

⁵⁶ *Id.* at 1613.

⁵⁷ Kurman Report at 4, n.20.

⁵⁸ *In re Zyprexa*, 489 F. Supp. 2d at 285; see also *In re Zolof*, 858 F.3d at 800 (failing to account for contrary evidence “undermines reliability”); *In re Zolof Prod. Liab. Litig.*, 26 F. Supp. 3d 449, 460-61 (E.D. Pa. 2014) (excluding expert’s opinion where expert’s report selectively discuss[es] studies” in favor of his or her opinion while failing to consider conflicting studies—i.e., cherry picking).

reconcile or even address the mainstream consensus opinions of other peer-reviewed research scientists.⁵⁹

B. DR. KURMAN FORMED HIS CAUSATION OPINIONS BASED ON A HEIGHTENED STANDARD OF CERTAINTY THAT WILL LIKELY CONFUSE AND MISLEAD JURIES

In arguing to exclude his opinions, the PSC detailed numerous examples of how Dr. Kurman applied a heightened standard of certainty to form his opinions. J&J does not take issue with the PSC's position that an expert should not use a heightened standard of certainty in assessing evidence and forming opinions, but J&J rejects the PSC's contention that Dr. Kurman did so in this instance.⁶⁰

J&J argues that the PSC has misconstrued Dr. Kurman's testimony, tried to trap Dr. Kurman with "gotcha" questions, and tried to mislead this Court with "cherry-picked" excerpts.⁶¹ Dr. Kurman described the standard he was applying in his own words. This Court need not rely on the PSC's or J&J's characterization; this Court can read the cited parts of the transcript to see the full context and determine for itself how to interpret his testimony.

⁵⁹ *McEwen v. Baltimore Washington Med. Ctr., Inc.*, 404 Fed. Appx. 789, 791-2 (4th Cir. 2010) (explaining the district court's exclusion of expert testimony was proper where the expert "failed to meaningfully account for medical literature at odds with [his] testimony" and "declar[ed] without explanation" that studies cited by opposing experts were unhelpful).

⁶⁰ Defs. Opp. at 25-29.

⁶¹ *Id.*

An analysis of general causation requires a determination of whether exposure to talc *is capable of* causing ovarian cancer.⁶² Dr. Kurman repeatedly went beyond this standard in denying the likelihood of general causation because he was not “convinced.” The PSC cited multiple examples of Dr. Kurman testifying in response to various questions that he needed to be “convinced,” (or variations -- each expressing a demand for a high level of certainty, *e.g.*, “not definitive” or “not necessarily.”).⁶³ Dr. Kurman’s application of an improper methodological standards warrants the exclusion of his opinions.

C. DR. KURMAN’S CRITICISMS OF DR. KANE’S OPINIONS DO NOT SATISFY DAUBERT STANDARDS

Dr. Kurman’s inadequate review of relevant scientific literature and improper reliance on his experience spills over into his inappropriate criticisms of Dr. Kane. Dr. Kurman is critical of Dr. Kane’s opinions on four topics: (1) her comparison of talcum powder and asbestos (and their related diseases); (2) her recognition that talcum powder can cause chronic inflammation on a cellular level that, like similar types of inflammation, can cause neoplastic lesions that are precursors to cancer; (3) her recognition of numerous studies that have identified talc in gynecologic tissue; (4) and her recognition that talc can and does migrate from the perineum to the

⁶² *Magistrini*, 180 F. Supp. 2d at 590; *see also In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016).

⁶³ *See* PSC Brief at 17-24.

ovaries. But Dr. Kurman's criticisms lack support and do not meet the *Daubert* threshold.

J&J's brief reflects a misunderstanding of the PSC's position. The PSC agrees that experts are permitted to critique other experts' opinions – but only if their alternative opinions and related criticisms are grounded in science and based on a reliable methodology. Dr. Kurman's opinions are based only on his unrelated experience in pathology. For an expert to be permitted to express any opinion, the expert must have a reliable methodology to support the opinion and cannot simply say, he disagrees, without saying more and providing a reliable basis for the disagreement.

1. Analogies to asbestos and mesothelioma

Dr. Kurman is critical of Dr. Kane's asbestos/talcum powder and mesothelioma/high grade serous ovarian carcinoma (HGSC) analogy, but his only support (other than his claim of experience) for his critique of Dr. Kane's pointing out similarities was to point out that there are differences. But it does not follow that simply because there are differences, that there are not also important similarities. J&J fails to address this issue.

J&J does not challenge the PSC's assertions regarding the limits of Dr. Kurman's qualifications to testify where the principal basis for his opinions is his experience. Dr. Kurman acknowledged *three times* in his deposition that he is not

an expert on asbestos and asbestos-related diseases.⁶⁴ Accordingly, Dr. Kurman's opinions about asbestos, its carcinogenic effects on tissue, and his criticism of Dr. Kane's asbestos/talc and mesothelioma/high grade serous ovarian carcinoma (HGSC) analogies should be precluded because he does not base his opinions on scientific evidence and, instead, relies only on his limited experience. In his report, Dr. Kurman criticized Dr. Kane's analogy of ovarian mesothelioma and HGSC, without providing scientific support. When confronted with actual data supporting Dr. Kane's comparison of ovarian mesothelioma and HGSC, Dr. Kurman acknowledged that HGSC (the subtype of 80% of all ovarian cancers) and ovarian mesothelioma are, in fact, so pathologically similar that even experienced pathologists confused the two for decades.⁶⁵

2. Inflammation

Dr. Kurman also criticizes Dr. Kane's opinions (supported by numerous citations) that chronic inflammation plays an important role in the development of ovarian cancer. Chronic inflammation as a pathway to ovarian carcinogenesis is nearly universally accepted by cancer researchers. J&J argues that Dr. Kurman's

⁶⁴ Kurman Dep. at 82:13-17 ("I'm not an expert on mesothelioma and asbestosis."); *see also*, Kurman Dep. at 90:8-12 ("I'm not an expert on the different types of asbestos."); and 91:15-17 ("...when it comes to the specifics of the composition of asbestos or, for that matter, talc, I would defer to a mineralogist.").

⁶⁵ *Id.* at 233:22-234:18.

opinions that are critical of Dr. Kane in this area are reliable because of his pathology experience.⁶⁶ However, Dr. Kurman's reliance on his expertise in lieu of scientific evidence is not only undermined by his admission that he is not an expert in cancer biology,⁶⁷ but also because he did not read the available cell studies observing talc's effect on cells and attempt to reconcile those studies with his contrary opinion.⁶⁸ Dr. Kurman's *general* pathology "experience" simply does not provide an adequate basis under *Daubert* for his critique of Dr. Kane's talcum powder-related causation opinions, which she supported with scientific evidence.

In addition to ignoring multiple studies on inflammation, when questioned about the International Agency for Research on Cancer's (IARC's) monograph on carcinogens, Dr. Kurman acknowledged that IARC adopted the chronic inflammation pathway to carcinogenesis with asbestos and lung cancer.⁶⁹ But he was unaware that IARC also has identified asbestiform (fibrous) talc as carcinogenic to humans – in the same class as asbestos.⁷⁰ Because of his unfamiliarity with fibrous talc, Dr. Kurman omitted any discussion of it in his report and refused to testify

⁶⁶ Defs. Opp. at 33-34.

⁶⁷ Kurman Dep. at 35:12-17.

⁶⁸ *Id.* at 19:9-18.

⁶⁹ Kurman Dep. at 81:10-21.

⁷⁰ *Id.* at 102:11-17.

about it in his deposition.⁷¹ Dr. Kurman also failed to reconcile his current opinion, that the causal link between talc-induced inflammation and ovarian cancer is not biologically plausible, with what appears in his own most recent textbook, in a chapter entitled “Surface Epithelial Tumors of the Ovary,”⁷² under the section heading “Inflammation:”

It has been suggested that inflammation potentially incited by ovulation-induced surface damage by retrograde menstruation-induced salpingitis *or by the introduction of foreign material through the vagina and uterine cavity plays an important role in ovarian carcinogenesis.* Evidence of a pro-inflammatory microenvironment in endometriosis supports this hypothesis for type I tumors. High-grade serous carcinomas are associated with chronic salpingitis in 53 percent of cases, significantly more than 23 percent seen in nonserous tumors, *lending circumstantial support to this hypothesis.*⁷³ (emphasis added)

Dr. Kurman’s basis for now disavowing what was biologically plausible according to his textbook, and for disavowing the widely accepted chronic inflammation pathway to ovarian carcinogenesis, is essentially, “I’ve never actually seen it, therefore it cannot be.”⁷⁴ He states – without scientific support - that talc in ovarian tissue would evoke a giant cell granulomatous foreign body reaction (a type of inflammatory response), and since he’s never observed that, talcum powder

⁷¹ *Id.* at 230:14-231:14.

⁷² *Id.* at 159:18 (Blaustein’s, Chapt. 14).

⁷³ *Id.* at 159:22-160:14.

⁷⁴ *Id.* at 148:7-149:14.

cannot cause cancer.⁷⁵ But studies show talc induces a macrophage reaction which Dr. Kurman acknowledges “is part of the inflammatory reaction,”⁷⁶ and giant cell granulomas are nothing more than agglomerations of macrophages.⁷⁷

In the absence of a review and consideration of relevant peer-reviewed scientific literature, Dr. Kurman’s pathology experience is wholly inadequate to make his talc-inflammation-carcinogenesis opinions reliable under *Daubert*. His “because I’ve never seen it” approach falls short of even the most liberal of *Daubert* interpretations and his criticisms of Dr. Kane on this topic must be excluded.

3. Migration and talcum powder observed in tissue

Dr. Kurman criticizes Dr. Kane’s opinion that talc particles and fibers can migrate from the perineum to the ovaries, as evidenced in part by the unequivocal identification of talc in gynecologic tissue of genital talc users in published studies. Although he once believed it to be true (as evidenced by his aforementioned statements in his textbooks), now as a hired expert for J&J, he apparently does not. Regardless, J&J fails to identify any methodology or scientific support for Dr. Kurman’s opinions that: 1) migration through the genital tract is not sufficiently

⁷⁵ *Id.*

⁷⁶ *Id.* at 85:17-23. For support, see Exhibit H to PSC Brief, McDonald, et al., Correlative Polarizing Light and Scanning Electron Microscopy for the Assessment of Talc in Pelvic Region Lymph Nodes, *Ultrastructural Pathology*, 2019.

⁷⁷ *Id.* at 84:24-85:5.

supported in Dr. Kane's report; 2) the studies Dr. Kane cites do not support her conclusion; 3) the inhalation and lymphatic transport of talc would mean that women who use perineal talc would also have talc-induced pulmonary disease; and 4) Dr. Kane's opinions are invalidated if ovarian cancer originates in the fallopian tubes. Each of these opinions lacks any basis other than the *ipse dixit* opinions of Dr. Kurman, and J&J's arguments to the contrary⁷⁸ do not cure this deficiency. For example, J&J points to no scientific support for Dr. Kurman's points about whether Dr. Kane's opinions about migration are supported by her citations, about inhalation and lymphatic transport, and about the origination of ovarian cancer in the fallopian tube.

Dr. Kurman offers only two animal studies⁷⁹ to support his opinions that talc cannot migrate to the ovaries, and then acknowledges neither really support his opinions.⁸⁰ He rejects the human studies that have for decades observed talc in gynecologic tissue by speculating, without any evidence, that the talc identified there

⁷⁸Defs. Opp. at 38-41.

⁷⁹ Kurman Dep. Exhibit 12, attached hereto as **Exhibit E** (Wehner (1985) study of 6 monkeys with only 30 talc applications); and Kurman Dep. Exhibit 13, attached hereto as **Exhibit F** (Boorman (1995) one-page report of rat and mouse study).

⁸⁰ Kurman Dep. at 281:15-18 (acknowledging that "30 applications over 45 days doesn't replicate long-term human genital talc use"), and 285:6-10 (agreeing that the "Boorman paper doesn't really tell you much about whether talc can migrate ...from the perineum to the ovaries in humans.")

must be post-surgical lab contamination.⁸¹ But the issue of contamination as the explanation was the subject of a study that Dr. Kurman had not considered,⁸² and that study concluded that contamination alone does not explain the observation of talc found in tissue in women exposed to talc.⁸³ The authors of that study stated: “we assessed tissue surface contamination as a factor explaining the high talc burden in some cases, as opposed to talc that migrated to the nodes from perineal exposure.”⁸⁴ Based on their peer-reviewed study, the authors concluded: “This study supports earlier observations that talc particles, from perineal exposure, can and do migrate to pelvic lymph nodes.”⁸⁵ As noted *supra*, Dr. Kurman’s reliance on the Heller study also does not support his opinion about contamination.

Also, as noted *supra* at page 12, fn. 30, Dr. Kurman does not reconcile his current opinion with what appears in Dr. Kurman’s most recent textbook, which recognizes that migration is both biologically plausible and actually occurs, by stating that inflammation resulting from “the introduction of foreign material through the vagina and uterine cavity plays an important role in ovarian carcinogenesis.”

⁸¹ *Id.* at 274:6-25.

⁸² *Id.* at 190:20-191:2.

⁸³ Exhibit H to PSC Brief, McDonald (2019).

⁸⁴ *Id.* at 2.

⁸⁵ *Id.* at 12.

All that J&J is left with is Dr. Kurman's experience, cherry-picked evidence, incomplete consideration and assessment of the evidence, failure to reconcile or explain contrary evidence, and *ipse dixit* opinions. And since he has never tried to detect talc in tissue, never studied others' findings of talc in tissue, and is not qualified to perform the type of analytical microscopy necessary to detect talc in tissue, his experience foundation crumbles as well.

III. CONCLUSION

For each of the foregoing reasons, the Court should grant Plaintiffs' *Daubert* motion to exclude the opinions of Robert Kurman, M.D.

Respectfully submitted,

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